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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,156	06/07/2005	Tadatake Oku	N0008.0001	1795

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	**PAPER NUMBER**
1656	
MAIL DATE	**DELIVERY MODE**
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,156	OKU ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *4,14,15 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-13 and 18-20* is/are rejected.

7)☒ Claim(s) *5,16,17 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/04; 1/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election without traverse of SEQ ID NO: 3 in the reply filed on April 27, 2007 is acknowledged.

The Examiner has searched SEQ ID NO: 3 and has examined the limitations of the broad claims, Claims 1-3, within the search of SEQ ID NO: 3. The Examiner has rejoined SEQ ID NO: 3, 8, and 10 because these sequences are so overlapping in subject matter that they have been reconsidered to be a single invention.

Thus, the heme peptide of Claim 4,14, 15, and 21 were not specifically examined and the Examiner has withdrawn these claims from further consideration because these claims are drawn to non-elected inventions.

Claims 1-3, 5-13, 16-20, and 22 have been examined as drawn to elected SEQ ID NO: 3, 8, and 10. The limitation of Claim 6 was found during the search of SEQ ID NO: 3 and therefore this sequence of Claim 6 was also examined.

Benefit of priority is to March 4, 2002.

The IDS filed January 17, 2007 was not signed. The IDS has been lined through and returned with this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 6, A1 can be Val-Glu-Lys. It appears that "Glu" should be "Gln". To advance prosecution, the Examiner has taken A1 to be Val-Gln-Lys.

Also, Claim 6 depends from Claim 1 wherein A1 must be a hydroxyl group or a peptide consisting of 1-20 amino acids. Thus, Claim 1 lacks antecedent basis for A1 to be a hydrogen group.

Claim 7 comprises non-elected subject matter. Therefore, Claim 7 does not particularly point out and distinctly claim the subject matter which the applicant regards as his elected invention.

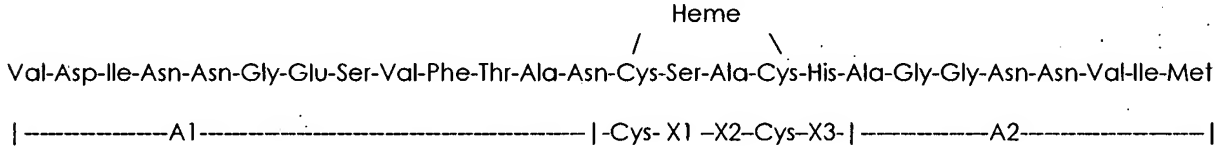
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being antipated by Sugimura et al. (1981; Studies on algal cytochromes. III. Amino acid sequence of cytochrome c-553 from brown alga, *Petalonia fascia*. J. Biochem. 90(4): 1213-1219).

Sugimura et al. teach cytochrome c-553 from brown alga comprising – Cys-Ser-Ala-Cys-His - . This cytochrome c-553 was cleaved into 3 peptide using BrCN (page 1214, para. 4) *before* the heme was removed from the peptide obtained by the BrCN cleaved (page 1214, para. 6).

Therefore, Sugimura et al. teach a heme peptide consisting of:

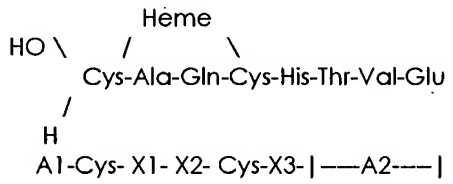


wherein A1 consists of13 amino acids (which is within 1-20 amino acids), A2 consists of 8 amino acids (which is within 1-50 amino acids), X1 is Ser and X2 is Ala (thus X1 and X2 are independently any amino acid residue), and X3 is His (wherein X3 is His, Lys, or Arg).

Claim 18, drawn to an NO scavenger comprising this heme peptide, is considered to be anticipated by Sugimura et al. because while Sugimua et al. do not teach that the heme peptide is an NO scavenger, this activity is considered to be an inherent property of heme peptide.

Claims 1-3, 6, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al. (1992; Temperature- and pH-dependent changes in the coordination sphere of the heme c group in the model peroxidase N^{α}-acetyl microperoxidase-8. J. Biol. Chem. 267(22): 15310-15318).

Wang et al. teach heme octapeptide MP-8 consisting of:



wherein A1 is a hydroxyl group, X1 is Ala and X2 is Gln (Claim 1, wherein X1 and X2 are independently any amino acid residue; Claim 2, wherein X1 and X2 are Ala, Gln, Lys, or Arg), X3 is His (Claim 1; wherein X3 is His, Arg, or Lys; Claim 3, wherein X3 is His), and A2 consists of 3 amino acids (Claim 1; which is within 1-50 amino acids).

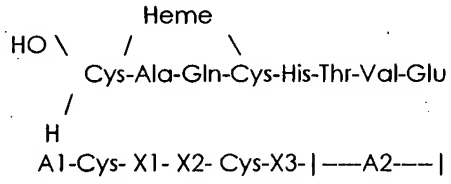
Claim 6 is anticipated because the A1 is a hydrogen (see also the 112. 2nd above), A2 is Thr-Val-Glu, X1 is Ala, X2 is Gln, and X3 is His.

Claims 18-20, drawn to an NO scavenger comprising this heme peptide, are considered to be anticipated by Wang et al. because while Wang et al. do not teach that the MP-8 is an NO scavenger, this activity is considered to be an inherent property of MP-8.

Note that Wang et al. teach that MP-8 is prepared by proteolytic digestion of Type VI horse heart cytochrome c; the purification of MP-8 was by RP-HPLC and not by gel filtration chromatography. See page 15310, right col., Experimental Procedures.

Claims 1-3, 6, 8-13, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Aron et al. 1986; Hemes and hemoproteins. 1: Preparation and analysis of the heme-containing octapeptide (microperoxidase-8) and identification of the monomeric form in aqueous solution. J. Inorg. Chem 27: 27-243).

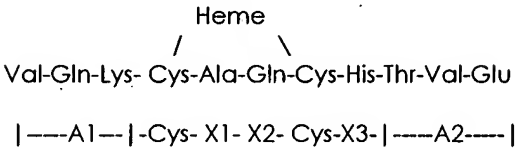
Aron et al. teach MP-8 and MP-11. MP-8 is depicted as follows –see Figure 1 of Aron et al.



Therefore, Aron et al. teach MP-8 wherein A1 is a hydroxyl group, X1 is Ala and X2 is Gln (Claim 1, wherein X1 and X2 are independently any amino acid residue; Claim 2, wherein X1 and X2 are Ala, Gln, Lys, or Arg), X3 is His (Claim 1; wherein X3 is His, Arg, or Lys; Claim 3, wherein X3 is His), and A2 consists of 3 amino acids (Claim 1; which is within 1-50 amino acids).

Claim 6 is anticipated because the A1 is a hydrogen (see also the 112, 2nd above), A2 is Thr-Val-Glu, X1 is Ala, X2 is Gln, and X3 is His.

MP-11 is depicted as follows:



Therefore, Aron et al. teach MP-11 wherein A1 is 3 amino acids (Claim 1, A1 is 1-10 amino acids), X1 is Ala and X2 is Gln (Claim 1, wherein X1 and X2 are independently any amino acid residue; Claim 2, wherein X1 and X2 are Ala, Gln, Lys, or Arg), X3 is His (Claim 1; wherein X3 is His, Arg, or Lys; Claim 3, wherein X3 is His), and A2 consists of 3 amino acids (Claim 1; which is within 1-50 amino acids).

Claim 6 is anticipated because the A1 is Val-Gln-Lys (see the 112, 2nd above), A2 is Thr-Val-Glu, X1 is Ala, X2 is Gln, and X3 is His.

Claims 18-20, drawn to an NO scavenger comprising this heme peptide, are considered to be anticipated by Aron et al. because while Aron et al. do not teach that the MP-8 or MP-11 is an NO scavenger, this activity is considered to be an inherent property of MP-8 and MP-11.

At page 230, Aron et al. prepared MP-8 from horse heart cytochome C using pepsin digestion and purified the MP-8 using a Biogel P6 column, a form of gel filtration chromatography. MP-11 was prepared using trypsin digestion and purifed using a Biogel P6 column – page 231, para 1.

Therefore, Aron et al. teach a method of producing heme peptides of Claims 1, 2, and 3 by digesting cytochrome C with a restriction enzyme and purifying the digest by gel filtration chromatography (Claim 8, 10, and 12), wherein the enzyme is trypsin (Claim 9, 11, and 13.),

Claims 5, 16, 17, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Art of Record:

Yamada et al. (2000; Characterization and amino acid sequences of cytomores c6 from two strains of green alga Chlorella vulgaris. Biosci. Biotechnol. Ciochem. 64(3): 628-632) teach cytochrome C6 in *Porphyra tenera* (Fig 2). This cytochrome comprises SEQ ID NO: 3, NO: 8, and NO:10 and was cleaved using CNBR *after* the heme was removed from the cytochrome. See page 631, para. 2, wherein the heme-free cytocromes C6 were obtained by reaction with N-nitrosulphenyl chloride and the CNBr-derived peptides where sequence. The CNBr derived peptide comprising SEQ ID NO: 3, NO: 8, and NO: 10 would have been longer than SEQ ID NO: 3, NO: 8, and NO: 10 at 41 amino acids, and there is no suggestion or motivation to leave the heme group on the peptide or replace it to the peptide.

Thus, Yamada et al. appears to be the closest prior art to the elected sequence SEQ ID NO: 3, which is the base sequence for SEQ ID NO: 8 and 10. While the prior art teaches full-length sequences comprising SEQ ID NO: 3, a thorough review of the art and of sequence searches did not result in obtaining references that taught these specific sequences, or these specific sequences bound to heme.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson Ph.D

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER